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Facsimile Transmission

To: Examiner Cynthia B. Wilder, Ph.D.
US Patent & Trademark Office, GAU 1637

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Re: Discussion Points for Telephone Interview of June 16, 2008

Your Ref.: US Application Nos. 10/550,797 and 11/392,479

Seed IP Ref.: 210121.609USPC and 210121.609C1

No. of Pages: 3 (including this page)

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Comments:

Examiner Wilder:

Per your request, attached is a summary of discussion points for our telephone interview of the noted applications, scheduled for Monday, June 16, 2008 at 1 p.m. DC time/10 a.m. Seattle time. Please let me know if you need additional information.

Julie A. Urvater, Ph.D.,

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FOR DISCUSSION ONLY
DISCUSSION POINTS FOR TELEPHONE INTERVIEW OF JUNE 16, 2008

Application No. : 10/550,797 and 11/392,479

For : DETECTION AND MONITORING OF LUNG CANCER

Examiner : Cynthia B. Wilder, Ph.D.

Fax : 571-273-0791

Art Unit : 1637

Docket No. : 210121.609USPC & 210121.609C1

USSN 10/550,797

- The Action asserts at page 5 that Applicant appears to be arguing “efficiency”. Discuss “complementarity” of the recited markers versus “efficiency”.
 - The present method detects greater than 90% of lung tumors, a level of detection that is not possible using the biomarkers individually. While the individual markers may have been known in the art, taken individually, they do not have this level of sensitivity.
- The Action asserts at page 5 that the presence of lung cancer is only recognized if one of the markers is elevated.
 - The method as presently claimed requires measuring the level of expression of at least two markers though detecting the expression of just one in a sample indicates the presence of lung cancer. Discuss potential claim amendment to clarify. (e.g., recite “three or more” or similar language; and/or recite “measuring the level of mRNA expression...”)

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DISCUSSION POINTS FOR TELEPHONE INTERVIEW OF JUNE 16, 2008

Application No. : 10/550,797 and 11/392,479

For : DETECTION AND MONITORING OF LUNG CANCER

Examiner : Cynthia B. Wilder, Ph.D.

Fax : 571-273-0791

Art Unit : 1637

Docket No. : 210121.609USPC & 210121.609C1

USSN 11/392,479

- Discuss “complementarity” of the recited markers versus “efficiency”.
- Discuss the concept that the present composition detects greater than 90% of lung tumors, a level of detection that is not possible using the markers individually. While the individual markers may have been known in the art, taken individually, they do not have this level of sensitivity.
- Henderson *et al* discloses over 2000 sequences. While the specification may have generic language indicating that multiple markers can be used in combination, given the complete lack of specific teaching therein, the skilled artisan would not know which of the 2000 sequences to combine in order to achieve the high level of sensitivity of lung cancer detection of the presently claimed composition.

As a note: the Action asserts that SEQ ID NO:1868 of Henderson *et al* refers to the L762P antigen. However, this sequence refers to L984P (see Henderson *et al* paragraph [0933]). To our knowledge, Henderson *et al* do not disclose the sequence of L762P.